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EXAMINER	
DWIVEDI, MAHESH H	

ART UNIT	PAPER NUMBER
2168	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

MN

Office Action Summary	Application No.	Applicant(s)	
	10/517,289	DOERING, AXEL	
	Examiner	Art Unit	
	Mahesh H. Dwivedi	2168	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Remarks

1. Receipt of Applicant's Amendment, filed on 08/22/2007, is acknowledged. The amendment includes the cancellation of claims 1-6, and the amending of claims 7, and 11-13.

The amended limitation of "wherein a diagnosis by an operator is not used in carrying out a similarity analysis" is entirely broad. For the purposes of examination, the examiner interprets "operator" as a human operator.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 101

3. The rejections raised in the office action mailed on 05/22/2007 have been overcome by the applicant's amendments received on 08/22/2007.

Claim Objections

4. Claim 7 is objected to because of the following informalities: The phrase "of comparison at a later time wherein a" should be changed to "of comparison at a later time, wherein a". Appropriate correction is required.

Claims 8-10 are objected to for incorporating the deficiencies of independent claim 7.

Specification

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Specifically, the claim terminology of "wherein a diagnosis by an operator is not sued in carrying out a similarity analysis" is not explicitly mentioned anywhere in the specification.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claim terminology of "wherein a diagnosis by an operator is not used in carrying out a similarity analysis" is not explicitly mentioned anywhere in the specification. The specification merely describes a claimed similarity process (see paragraph 11).

For reference, see MPEP 2173.05 (i), which states "Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff 'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement"

Claims 8-10 and 12-13 are rejected for incorporating the deficiencies of independent claims 7 and 11.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claim terminology of "wherein a diagnosis by an operator is not used in carrying out a similarity analysis" is indefinite as

there is no clear definition of what an operator is. For the purposes of examination, the examiner interprets "operator" as a human operator.

Claims 8-10 and 12-13 are rejected for incorporating the deficiencies of independent claims 7 and 11.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 7-13 are rejected under 35 U.S.C. 102(a) as being anticipated by **Sinclair et al.** (U.S. PGPUB 2002/0052551).

11. Regarding claim 7, **Sinclair** teaches a method comprising:

A) determining deviations from a stored comparison image and/or from a standard image created by evaluating a plurality of comparison images of a similar pathology (Paragraphs 19, 166-167, 231-232, 234, and 252-267); and/or

B) carrying out a similarity analysis by a stored comparison image, and/or by a standard image created by evaluating a plurality of comparison images of a similar pathology (Paragraphs 19, 72, 166-167, 231-232, 234, and 252-267); and

C) creating new images that are stored for purposes of comparison at a later time (Paragraphs 44 and 72); and

D) wherein a diagnosis by an operator is not used in carrying out a similarity analysis (Paragraphs 231 and 234).

The examiner notes that **Sinclair** teaches **"determining deviations from a stored comparison image and/or from a standard image created by evaluating a plurality of comparison images of a similar pathology"** as "Another significant element of this invention is one or more retinal grading algorithms that automatically evaluate the digital retinal images obtained by the screening subsystems for particular retinopathies. Generally, the RGAs operate in a lesion-based fashion, first identifying ophthalmologically significant retinal lesions or features by use of image processing

methods, and second evaluating and grading the retinopathy in view of the identified lesions by use of artificial intelligence/cognitive decision capabilities" (Paragraph 19), "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231), and "In somewhat more detail, the following lists DR lesions that are preferably detected and identified by all RGA algorithms. Sophisticated RGA algorithms for DR detect additionally the advantageous lesions. DR Lesions and Characteristics Preferably Identified...Fovea (or approximate foveal location)... Epi-retinal (or epi-papillary) neovascularization--size and distance to optic nerve head or fovea" (Paragraphs 252-265). The examiner further notes that **Sinclair** teaches **"carrying out a similarity analysis by a stored comparison image, and/or by a standard image created by evaluating a plurality of comparison images of a similar pathology"** as "Also, in preferred embodiments where prior retinal images are available and may be compared to a current retinal image, the time progression or regression of lesions may be identified. Then, detailed lesion information and lesion history may be taken into account in adjusting retinal image grading. For example, if a current image received a grade of level 2, but it contained lesions in critical anatomic regions as near the optic nerve head, or the fovea, or so forth, or contained rapidly growing or multiplying lesions, it may be promoted to grade level 3. Conversely, if a current image received a grade of level 3, but it contained regressing lesions in locations posing no threat of imminent visual impairment, it may be demoted to grade level 2 (or 2+) (Generally, grade level 3 signifies specialist consultation is recommended, while grade level 2 signifies that routine follow-up screening is recommended.)" (Paragraph 72), "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade

level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231), and "In somewhat more detail, the following lists DR lesions that are preferably detected and identified by all RGA algorithms. Sophisticated RGA algorithms for DR detect additionally the advantageous lesions. DR Lesions and Characteristics Preferably Identified...Fovea (or approximate foveal location)... Epi-retinal (or epi-papillary) neovascularization--size and distance to optic nerve head or fovea" (Paragraphs 252-265). The examiner further notes that **Sinclair** teaches **"creating new images that are stored for purposes of comparison at a later time"** as "identify, and characterize in the prior retinal images lesions from the pre-determined set lesions type, comparing the lesions detected in the image taken at the selected time with the lesions detected in the prior image to detect changes in the lesions, and performing a decision process that assigns a grade to the retinal image taken at the selected time in dependence on the identities and characteristics of the lesions detected in that image, and in dependence on the changes in the lesions detected in the comparing step" (Paragraph 44) and "Also, in preferred embodiments where prior retinal images are available and may be compared to a current retinal image, the time progression or regression of lesions may be identified. Then, detailed lesion information and lesion history may be taken into account in adjusting retinal image grading. For example, if a current image received a grade of level 2, but it contained lesions in critical anatomic regions as near the optic nerve head, or the fovea, or so forth, or contained rapidly growing or multiplying lesions, it may be promoted to grade level 3. Conversely, if a current image received a grade of level 3, but it contained regressing lesions in locations posing no threat of imminent visual impairment, it may be demoted to grade level 2 (or 2+) (Generally, grade level 3 signifies specialist consultation is recommended, while grade level 2 signifies that routine follow-up screening is recommended.)" (Paragraph 72). The examiner further notes that **Sinclair** teaches **"wherein a diagnosis by an operator is not used in carrying out a similarity analysis"** as "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number

and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231) and "The highest level of RGA processing is illustrated in FIG. 3C at steps 100-102. Step 100 represents the determination by the image quality algorithms that a set of acquired images is suitable for RGA grading. Step 101 processes each image to detect and identify ophthalmologic lesions (as just defined above) and returns lesion-by-lesion information including lesion type, lesion size, lesion location, and so forth. Steps 103-111 further describe lesion processing. Finally, step 102 uses all the lesion information returned from step 101 to arrive at an overall retinopathy grading and evaluation. For example, this step may be implemented as an expert system that simulates the reasoning of an ophthalmologist presented with the accumulated lesion information. Thus, grading rules may be executed in view of the accumulated lesion information" (Paragraph 234).

Regarding claim 8, **Sinclair** further teaches a method comprising:
A) wherein the evaluation is carried out by averaging extracted features (Paragraphs 305-344).

The examiner notes that **Sinclair** teaches **"wherein the evaluation is carried out by averaging extracted features"** as "The following lists exemplary and non-limiting statistical information which may be obtained and accumulated in an OSS implementation. The following statistical parameters may be accumulated to aid in quality control and oversight of an OSS. Exemplary Quality Control Statistics...Percent of eyes with more advanced lesions noted in each field (1, 2, 3, 4 or 5) without equivalent lesions noted in other fields. Percent of patients who complied with recommendation for screening and follow-up screening; time interval between receipt of recommendation/referral by patient and actual follow-up screening. Sensitivity & specificity of the grading algorithm as compared with the gold standard of grading performed by the retinal specialist--for each eye (variance with age, pupil size, necessity

for dilation, presence of cataract)" (Paragraphs 305-344). The examiner further notes that the various statistical analysis of the fundus properties of patients is analogous to an averaging function.

Regarding claim 9, **Sinclair** further teaches a method comprising:
A) wherein deviations are determined and/or the similarity analysis is carried out on the basis of a gray-value analysis and/or an analysis of color histograms and/or a structure analysis (Paragraphs 19, 166-167, 231-232, 234, and 252-267).

The examiner notes that **Sinclair** teaches **"wherein deviations are determined and/or the similarity analysis is carried out on the basis of a gray-value analysis and/or an analysis of color histograms and/or a structure analysis"** as "Another significant element of this invention is one or more retinal grading algorithms that automatically evaluate the digital retinal images obtained by the screening subsystems for particular retinopathies. Generally, the RGAs operate in a lesion-based fashion, first identifying ophthalmologically significant retinal lesions or features by use of image processing methods, and second evaluating and grading the retinopathy in view of the identified lesions by use of artificial intelligence/cognitive decision capabilities" (Paragraph 19), "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231), and "In somewhat more detail, the following lists DR lesions that are preferably detected and identified by all RGA algorithms. Sophisticated RGA algorithms for DR detect additionally the advantageous lesions. DR Lesions and Characteristics Preferably Identified...Fovea (or approximate foveal location)... Epi-retinal (or epi-papillary) neovascularization--size and distance to optic nerve head or fovea" (Paragraphs 252-265). The examiner further notes that paragraph 11 of the

specification of the instant application defines a structural analysis of as "classification and quantification of structures at the ocular fundus (e.g., papilla, fovea)".

Regarding claim 10, **Sinclair** further teaches a method comprising:
A) wherein an extraction of vascular tree parameters is carried out (Paragraphs 268-272).

The examiner notes that **Sinclair** teaches **"wherein deviations are determined and/or the similarity analysis is carried out on the basis of a gray-value analysis and/or an analysis of color histograms and/or a structure analysis"** as "Second, diameter and tortuosity measurements for major vessel abnormalities including: Major artery tortuosity--deviations of 1.sup.st, 2.sup.nd, and 3.sup.rd order arteries from a straight line (point-to-point); also requires determination of whether the deviations are caused by branchings or by deviations between branchings; in other words, if a vessel branches unequally (daughter vessels are unequal in caliber), this causes a deviation of the large parent vessel into the larger of the two daughter vessels, Major vein tortuosity--deviations of 1.sup.st, 2.sup.nd, and 3.sup.rd order veins from a straight line (point-to-point) and whether deviations are caused by branchings or by deviations in between branchings, Major artery diameter (and variation in diameter) versus distance along vessel starting at the optic nerve head--for 1.sup.st and 2.sup.nd order vessels; second order vessels are defined as either two daughter vessels after an equal branching (branching in which both daughter vessels are of same caliber) or the smaller caliber vessel of the daughter vessels in an unequal branching, Major vein diameter (and variation in diameter) versus distance along vessel--for 1.sup.st and 2.sup.nd order vessels." (Paragraphs 268-272).

Regarding claim 11, **Sinclair** teaches a system comprising:
A) a fundus camera for recording the ocular fundus (Paragraphs 88-89, and 184);
B) an image storage for storing recorded fundus images (Paragraphs 24, 119-121, 166, and 228); and

C) means for evaluating the recorded fundus images of a similar pathology further comprising means for gray-value analysis and/or means for preparing color histograms and/or means for structure analysis (Paragraphs 19, 166-167, 231-232, 234, and 252-267); and

D) a comparison unit connected to the image storage (Paragraphs 44 and 72);

E) wherein the comparison unit compares images recording in the image storage and creates new images of a similar pathology (Paragraphs 44 and 72); and

F) wherein a diagnosis by an operator is not used in carrying out a similarity analysis (Paragraphs 231 and 234).

The examiner notes that **Sinclair** teaches **"a fundus camera for recording the ocular fundus"** as "For image capture and acquisition, preferably a non-mydriatic retinal camera is used to acquire retinal images in order to avoid the patient inconvenience of pupil dilation (mydriasis)" (Paragraph 88), "The present invention may use a wide range of non-mydriatic cameras, including commercially-available cameras from, e.g., Canon, Nikon, and so forth, and also including specially designed and built cameras. From whatever source, preferred cameras have should have optics capable of acquiring up to 45.degree. retinal fields through pupils down to 2.0 mm in diameter with adequate image contrast and resolution" (Paragraph 89), and "retinal (fundus) camera with CCD sensors" (Paragraph 184). The examiner further notes that **Sinclair** teaches **"an image storage for storing recorded fundus images"** as "The central database ("CDB") is an on-line (or otherwise efficiently accessible) storage repository of the data generated in an OSS system. The CDB stores patient oriented data such as original image data from patient screening examinations, results of RGA screening including images annotated or marked-up with lesion identification, associated patient identification, demographics, and screening/examination history, results of manual ophthalmologist grading process including any annotated images, referrals and reports" (Paragraph 119) and "The CDB has several uses in an OSS, and its centralized image (also possible with distributed database architectures) provides several advantages. Its principal use is to provide physicians, specialists, ophthalmologists, and other users with access to current images as well as the results of any prior studies, regardless of

where acquired. This historical record permits an objective and quantitative evaluation, either by automatic algorithmic processes or by manual physician examination, of the status and progression of the ocular disease in individual patients" (Paragraph 121). The examiner further notes that **Sinclair** teaches **"means for evaluating the recorded fundus images of a similar pathology further comprising means for gray-value analysis and/or means for preparing color histograms and/or means for structure analysis"** as "Another significant element of this invention is one or more retinal grading algorithms that automatically evaluate the digital retinal images obtained by the screening subsystems for particular retinopathies. Generally, the RGAs operate in a lesion-based fashion, first identifying ophthalmologically significant retinal lesions or features by use of image processing methods, and second evaluating and grading the retinopathy in view of the identified lesions by use of artificial intelligence/cognitive decision capabilities" (Paragraph 19), "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231), and "In somewhat more detail, the following lists DR lesions that are preferably detected and identified by all RGA algorithms. Sophisticated RGA algorithms for DR detect additionally the advantageous lesions. DR Lesions and Characteristics Preferably Identified...Fovea (or approximate foveal location)... Epi-retinal (or epi-papillary) neovascularization--size and distance to optic nerve head or fovea" (Paragraphs 252-265). The examiner further notes that paragraph 11 of the specification of the instant application defines a structural analysis of as "classification and quantification of structures at the ocular fundus (e.g., papilla, fovea)". The examiner further notes that **Sinclair** teaches **"a comparison unit connected to the image storage"** as "identify, and characterize in the prior retinal images lesions from the pre-determined set lesions type, comparing the lesions detected in the image taken at the selected time with the lesions detected in the prior image to detect changes in the

lesions, and performing a decision process that assigns a grade to the retinal image taken at the selected time in dependence on the identities and characteristics of the lesions detected in that image, and in dependence on the changes in the lesions detected in the comparing step" (Paragraph 44) and "Also, in preferred embodiments where prior retinal images are available and may be compared to a current retinal image, the time progression or regression of lesions may be identified. Then, detailed lesion information and lesion history may be taken into account in adjusting retinal image grading. For example, if a current image received a grade of level 2, but it contained lesions in critical anatomic regions as near the optic nerve head, or the fovea, or so forth, or contained rapidly growing or multiplying lesions, it may be promoted to grade level 3. Conversely, if a current image received a grade of level 3, but it contained regressing lesions in locations posing no threat of imminent visual impairment, it may be demoted to grade level 2 (or 2+) (Generally, grade level 3 signifies specialist consultation is recommended, while grade level 2 signifies that routine follow-up screening is recommended.)" (Paragraph 72). The examiner further notes that **Sinclair** teaches **"wherein the comparison unit compares images recording in the image storage and creates new images of a similar pathology"** as "identify, and characterize in the prior retinal images lesions from the pre-determined set lesions type, comparing the lesions detected in the image taken at the selected time with the lesions detected in the prior image to detect changes in the lesions, and performing a decision process that assigns a grade to the retinal image taken at the selected time in dependence on the identities and characteristics of the lesions detected in that image, and in dependence on the changes in the lesions detected in the comparing step" (Paragraph 44) and "Also, in preferred embodiments where prior retinal images are available and may be compared to a current retinal image, the time progression or regression of lesions may be identified. Then, detailed lesion information and lesion history may be taken into account in adjusting retinal image grading. For example, if a current image received a grade of level 2, but it contained lesions in critical anatomic regions as near the optic nerve head, or the fovea, or so forth, or contained rapidly growing or multiplying lesions, it may be promoted to grade level 3. Conversely, if a

current image received a grade of level 3, but it contained regressing lesions in locations posing no threat of imminent visual impairment, it may be demoted to grade level 2 (or 2+) (Generally, grade level 3 signifies specialist consultation is recommended, while grade level 2 signifies that routine follow-up screening is recommended.)" (Paragraph 72). The examiner further notes that **Sinclair** teaches **"wherein a diagnosis by an operator is not used in carrying out a similarity analysis"** as "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231) and "The highest level of RGA processing is illustrated in FIG. 3C at steps 100-102. Step 100 represents the determination by the image quality algorithms that a set of acquired images is suitable for RGA grading. Step 101 processes each image to detect and identify ophthalmologic lesions (as just defined above) and returns lesion-by-lesion information including lesion type, lesion size, lesion location, and so forth. Steps 103-111 further describe lesion processing. Finally, step 102 uses all the lesion information returned from step 101 to arrive at an overall retinopathy grading and evaluation. For example, this step may be implemented as an expert system that simulates the reasoning of an ophthalmologist presented with the accumulated lesion information. Thus, grading rules may be executed in view of the accumulated lesion information" (Paragraph 234).

Regarding claim 12, **Sinclair** further teaches a system comprising:
A) a means for determining deviations from a stored comparison image and/or from a standard image created by evaluating a plurality of comparison images, and/or a means for carrying out a similarity analysis by a stored comparison image and/or by a standard image created by evaluating a plurality of comparison images (Paragraphs 19, 166-167; 231-232, 234, and 252-267).

The examiner notes that **Sinclair** teaches **"a means for determining deviations from a stored comparison image and/or from a standard image created by evaluating a plurality of comparison images, and/or a means for carrying out a similarity analysis by a stored comparison image and/or by a standard image created by evaluating a plurality of comparison images"** as "Another significant element of this invention is one or more retinal grading algorithms that automatically evaluate the digital retinal images obtained by the screening subsystems for particular retinopathies. Generally, the RGAs operate in a lesion-based fashion, first identifying ophthalmologically significant retinal lesions or features by use of image processing methods, and second evaluating and grading the retinopathy in view of the identified lesions by use of artificial intelligence/cognitive decision capabilities" (Paragraph 19), "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231), and "In somewhat more detail, the following lists DR lesions that are preferably detected and identified by all RGA algorithms. Sophisticated RGA algorithms for DR detect additionally the advantageous lesions. DR Lesions and Characteristics Preferably Identified...Fovea (or approximate foveal location)... Epi-retinal (or epi-papillary) neovascularization--size and distance to optic nerve head or fovea" (Paragraphs 252-265).

Regarding claim 13, **Sinclair** further teaches a system comprising:
A) wherein means are provided for determining deviations from a stored comparison image and/or from a standard image created by evaluating a plurality of comparison images, and/or means are provided for similarity analysis by a stored comparison image and/or a standard image created by evaluating a plurality of comparison images (Paragraphs 19, 166-167, 231-232, 234, and 252-267).

The examiner notes that **Sinclair** teaches **"wherein means are provided for determining deviations from a stored comparison image and/or from a standard image created by evaluating a plurality of comparison images, and/or means are provided for similarity analysis by a stored comparison image and/or a standard image created by evaluating a plurality of comparison images"** as "Another significant element of this invention is one or more retinal grading algorithms that automatically evaluate the digital retinal images obtained by the screening subsystems for particular retinopathies. Generally, the RGAs operate in a lesion-based fashion, first identifying ophthalmologically significant retinal lesions or features by use of image processing methods, and second evaluating and grading the retinopathy in view of the identified lesions by use of artificial intelligence/cognitive decision capabilities" (Paragraph 19), "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231), and "In somewhat more detail, the following lists DR lesions that are preferably detected and identified by all RGA algorithms. Sophisticated RGA algorithms for DR detect additionally the advantageous lesions. DR Lesions and Characteristics Preferably Identified...Fovea (or approximate foveal location)... Epi-retinal (or epi-papillary) neovascularization--size and distance to optic nerve head or fovea" (Paragraphs 252-265).

Response to Arguments

12. Applicant's arguments filed 08/22/2007 have been fully considered but they are not persuasive.

Applicants argue on page 5 that **"Specifically, Sinclair fails to teach or suggest that a diagnosis by an operator is not used in carrying out a similarity analysis. In contrast to the teachings of Sinclair, the claimed invention provides that the digital images taken of the eyes as wells as the images existing in a**

database are analyzed and compared by means of purely image-based parameters". However, the examiner wishes to point to paragraphs 231 and 234 of **Sinclair** which state "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231) and "The highest level of RGA processing is illustrated in FIG. 3C at steps 100-102. Step 100 represents the determination by the image quality algorithms that a set of acquired images is suitable for RGA grading. Step 101 processes each image to detect and identify ophthalmologic lesions (as just defined above) and returns lesion-by-lesion information including lesion type, lesion size, lesion location, and so forth. Steps 103-111 further describe lesion processing. Finally, step 102 uses all the lesion information returned from step 101 to arrive at an overall retinopathy grading and evaluation. For example, this step may be implemented as an expert system that simulates the reasoning of an ophthalmologist presented with the accumulated lesion information. Thus, grading rules may be executed in view of the accumulated lesion information" (Paragraph 234). The examiner further wishes to state that the amended limitation merely states "a diagnosis by an operator", without defining what an operator is. Since (as stated above) the examiner interprets an operator as a human operator, **Sinclair's** automated system broadly teaches the amended claim.

Applicants argue on page 5 that **"It should be noted that in the system of Sinclair, a diagnosis of the image data is necessary, wherein in the claimed invention, there is no need for a diagnosis on the part of the operator. Instead, the image data is compared by means of the characteristic features present in the images"**. However, the examiner wishes to point to paragraphs 44 and 234 of **Sinclair** which state "identify, and characterize in the retinal image lesions from a pre-determined set lesions type, wherein the pre-determined set of lesion types describe visual features characteristically found in retinas with the selected retinopathy,.

processing at least one digitally-encoded retinal image of the patient taken at least one time prior to the selected time to detect, identify, and characterize in the prior retinal images lesions from the pre-determined set lesions type, comparing the lesions detected in the image taken at the selected time with the lesions detected in the prior image to detect changes in the lesions, and performing a decision process that assigns a grade to the retinal image taken at the selected time in dependence on the identities and characteristics of the lesions detected in that image, and in dependence on the changes in the lesions detected in the comparing step" (Paragraph 44) and "The highest level of RGA processing is illustrated in FIG. 3C at steps 100-102. Step 100 represents the determination by the image quality algorithms that a set of acquired images is suitable for RGA grading. Step 101 processes each image to detect and identify ophthalmologic lesions (as just defined above) and returns lesion-by-lesion information including lesion type, lesion size, lesion location, and so forth. Steps 103-111 further describe lesion processing. Finally, step 102 uses all the lesion information returned from step 101 to arrive at an overall retinopathy grading and evaluation. For example, this step may be implemented as an expert system that simulates the reasoning of an ophthalmologist presented with the accumulated lesion information. Thus, grading rules may be executed in view of the accumulated lesion information" (Paragraph 234). The examiner further wishes to state that **Sinclair's** method clearly identifies problems with eyes via discerning characteristics of captured images.

Applicants argue on page 5 that **"Thus, instead of diagnosis by the operator, which always represents a source of subjective error, the analysis and comparison of images in the claimed invention is carried out in a purely computer based manner without being influenced by the operator"**. However, the examiner wishes to point to paragraphs 231 and 234 of **Sinclair** which state "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with

similar cumulative lesion information" (Paragraph 231) and "The highest level of RGA processing is illustrated in FIG. 3C at steps 100-102. Step 100 represents the determination by the image quality algorithms that a set of acquired images is suitable for RGA grading. Step 101 processes each image to detect and identify ophthalmologic lesions (as just defined above) and returns lesion-by-lesion information including lesion type, lesion size, lesion location, and so forth. Steps 103-111 further describe lesion processing. Finally, step 102 uses all the lesion information returned from step 101 to arrive at an overall retinopathy grading and evaluation. For example, this step may be implemented as an expert system that simulates the reasoning of an ophthalmologist presented with the accumulated lesion information. Thus, grading rules may be executed in view of the accumulated lesion information" (Paragraph 234). The examiner further wishes to state that **Sinclair's** method is clearly computer based and not subject to human error (see "This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information").

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 6,757,409 issued to **Marshall et al.** on 29 June 2004. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. PGPUB 2004/0156016 issued to **Kerr et al.** on 12 August 2004. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 7,055,955 issued to **Kishida et al.** on 06 June 2006. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,755,526 issued to **Shibata** on 29 June 2004. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,112,114 issued to **Dreher** on 29 August 2000. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,409,342 issued to **Ohnyuma et al.** on 25 June 2002. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,928,193 issued to **Gersten** on 09 August 2005. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 5,287,129 issued to **Sano et al.** on 15 February 1994. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,053,865 issued to **Sugiyama et al.** on 25 April 2000. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 5,993,001 issued to **Bursell et al.** on 13 November 1999. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 5,557,9471 issued to **Barber et al.** on 26 November 1996. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,766,041 issued to **Golden et al.** on 20 July 2004. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,453,057 issued to **Marshall et al.** on 17 September 2002. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,714,672 issued to **Berestov et al.** on 30 March 2004. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,,179,421 issued to **Pang** on 30 January 2001. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,840,933 issued to **Pang et al.** on 11 January 2005. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 7,025,459 issued to **Cronsweet et al.** on 11 April 2006. The subject matter disclosed therein is pertinent to that of claims 7-13 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahesh Dwivedi whose telephone number is (571) 272-2731. The examiner can normally be reached on Monday to Friday 8:20 am – 4:40 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Vo can be reached (571) 272-3642. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mahesh Dwivedi
Patent Examiner
Art Unit 2168

MHD
September 07, 2007

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